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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,154	04/26/2006	Eiichi Kitazono	Q94633	1395

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EXAMINER	
SCHMIDTMANN, BAHAR	

ART UNIT	PAPER NUMBER
4131	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,154	KITAZONO ET AL.	
	Examiner	Art Unit	
	BAHAR SCHMIDTMANN	4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☒ Claim(s) *1-8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/28/2007, 2/15/2007, 4/26/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a national stage entry of PCT/JP04/16285, filed 27 October 2004; and claims benefit of foreign priority document JAPAN 2003-368540, filed 29 October 2003, document JAPAN 2004-205682, filed 13 July 2004, and document JAPAN 2004-274775, filed 22 September 2004. The foreign priority documents are in Japanese.

Claims 1-8 are pending in the current application and are examined on the merits herein.

Claim Objections

Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The recitation of an intended use, chemical activity or functional description of some "additional" property for a compound (or moiety/functionality attached to a chemical core) or composition containing the same in a dependent claim, must result in a tangible structural difference between the product of the independent claim and the product set forth in the dependent claim. In the absence of said structural difference between the product of the independent claim and that of the dependent claim, said dependent claim is seen to be a substantial duplicate, and said recitation is not afforded critical weight and fails to further limit the product in said dependent claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 8 provides for the "method of using a hyaluronic acid" but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 claim a hyaluronic acid compound represented by formula (1)' and claims 6-8 claim a hyaluronic acid compound represented by the formula (1). Claim 1 states that "R^0 is a group represented by the following formula (1)'-a, -OH, or –ONa..." Claim 6 similarly states that "R is a group represented by the following formula (1)-a, -OH, or -ONa..." The presence of the charged phosphatidyl ethanolamine could be interpreted as requiring the compound to be a salt with a counter-ion or as an ionized form of the free acid in solution. It is unclear if Applicant intends to claim the ionized, neutral and salt forms of phosphatidyl ethanolamine, or if Applicant intends to claim the ionized, neutral and salt forms of the free acid.

Claim 8 provides for the "method of using a hyaluronic acid compound", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katsukiyo et al. (US Patent No. 5,733,892, cited in the Information Disclosure

Statement) in view of Shigehisa et al. (JP 06-072893, cited by Applicant in the Information Disclosure Statement)

Katsukiyo et al. teaches compounds prepared by linking glycosaminoglycan to phospholipid or lipid (abstract). Examples 4 and 5 provide for the preparation of L-(α-phosphatidyl)ethanolamine dipalmitoyl-linked glycosaminoglycans (GAG-PPEADP). Specifically, Lot No. 1000 provides for the compound HA1-PPEADP (columns 47-50, tables L and M).

Katsukiyo et al. teaches the contents of phospholipid or lipid portions in the phospholipid- or lipid-linked glycosaminoglycans represented by formula (VIII) may range from 0.005 to 50% (column 34 lines 40-44). Applicant's disclosure of hydrogel includes the use of 1 to 100 equivalents of phosphatidyl ethanolamine based on 100 equivalents of the carboxyl group of hyaluronic acid (specification, column 6 lines 22-35 and column 7 lines 1-13). The range presented by Katsukiyo et al. is within the range provided in the disclosure.

Katsukiyo et al. also teaches the injectable solutions of the salt forms of the phospholipid- or lipid-linked glycosaminoglycan (column 35, lines 1-3). A syringe containing said injectable solution can be considered as a molded form of hyaluronic acid.

Katsukiyo et al. does not specifically disclose the embodiment of phosphatidyl ethanolamine where the acyl groups are unsaturated. However, Shigehisa et al. teaches an antirheumatic compound which uses lipid conjugates of glycosaminoglycans or its salts, while Katsukiyo teaches their use as metastasis inhibitors (claim 1).

Shigehisa et al. teaches that lipid-binding GAG weakens the inflammation of synovial tissue, i.e. the lipid-binding GAG reduces the neoplasia of a synovial cell, fibrin deposition, the coagulation of lymphocytes, as well as prevent the extension of pannus involved in rheumatism (paragraph 0100). From the disclosure provided by Shigehisa et al., it is understood that lipid-binding GAG is useful both as an antirheumathoid and metastasis (i.e. neoplastic) inhibitor.

Shigehisa et al. teaches the binding of the carboxylic acid functional group of uronic acid in a glycosaminoglycan with the amine group of a lipid (paragraph 0016, chemical formula 1, C). Shigehisa et al. also teaches that the glycosaminoglycan used can be hyaluronic acid (paragraph 0020) and that the chain length and degree of unsaturation of an acyl group in a lipid are not limited (paragraph 0021).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Katsukiyo et al. with the teaching of Shigehisa et al because the substitution of one phospholipid, such as dipalmitoylphosphatidyl ethanolamine for dioleoylphosphatidyl ethanolamine would have been an obvious substitution to the skilled artisan in this field.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mrs. Bahar Schmidtmann whose telephone number is (571)270-1326. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624

/Bahar Schmidtmann/
Patent Examiner, Art Unit 4131